K061060

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Exhibit D: **510(k) Summary of Safety and Effectiveness**

Submitter's Name and Address:

Tissue Technologies Holdings LLC
800 East Leigh St, Unit 51
Richmond, VA 23219
804-225-7447

JUL - 3 2006

Contact Person: Yousef Mohajer

Name of Medical Device:

Classification Name:	Dressing, Wound
Common/Usual Name:	Dressing
Proprietary Name:	TT101 Wound Care Dressing

Substantial Equivalence: TT101 Wound Care Dressing is substantially equivalent to: PROMOGRAN Matrix Wound Dressing (K014129) manufactured by Johnson & Johnson Medical Ltd., Gargrave, North Yorkshire, BD23 3RX, United Kingdom

Device Classification: Currently, wound dressings containing animal derived materials are unclassified by United States Food and Drug Administration's Center for Devices and Radiological Health

Device Description: TT101 Wound Care Dressing is a sterile primary dressing comprised of phosphorylated cellulose, formed into a sheet approximately 3 mm thick cut into various size pieces. When placed on a wound, the dressing provides a moist wound environment that is supportive to wound healing.

Indications for Use: Wound Dressing is indicated for the management of exuding wounds including:
Diabetic ulcers
Venous ulcers
Ulcers caused by mixed vascular etiologies
Full thickness and partial thickness wounds
Donor sites and other bleeding surface wounds
Abrasions
Traumatic wounds healing by secondary intention
Dehisced surgical wounds

Safety: Biocompatibility studies have demonstrated TT101 Wound Care Dressing to be non-toxic, non-irritating, non-sensitizing, and non-cytotoxic.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 3 2006

Tissue Technologies Holdings
c/o Bio-Track LLC
Mark Licata
President
800 East Leigh Street
Richmond, Virginia 23219

Re: K061060
Trade/Device Name: TT101 Wound Care Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: June 21, 2006
Received: June 21, 2006

Dear Mr. Licata:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally

marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit C

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Indications for Use

510(k) Number (if known): K061060

Device Name: TT101 Wound Care Dressing

Indications For Use: The TT101 Wound Care Dressing is indicated for the management of exuding wounds including:

Diabetic ulcers
Venous ulcers
Ulcers caused by mixed vascular etiologies
Full thickness and partial thickness wounds
Donor sites and other bleeding surface wounds
Abrasions
Traumatic wounds healing by secondary intention
Dehisced surgical wounds

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K061060

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)